

REMARKS

The claims are 4 and 5. Claims 1-3 are canceled and claim 2 is incorporated into new claim 4. Claim 4 also now recites excluded compounds, supported by page 3, lines 3-6.

Claim 1-3 is rejected under 35 U.S.C. § 103 as obvious over Leahy, United States Patent No. 6,281,192. The rejection is traversed. Leahy teaches an ophthalmic composition for the treatment of dry eye, essentially a loss of tear film. The teaching of Leahy is the use of the glycoprotein mucin to relieve the symptoms of this condition. Leahy teaches that a preservative may be present (col. 8, line 60). If present, Leahy teaches very small amounts of various compounds, including polyhexamethylene biguanide (15 ppm). There is no teaching or suggestion in Leahy to select biguanide in preference to any of the other preservatives. Nor is there any teaching or suggestion to increase the amount of any of the compounds to the levels claimed herein, since such increased amounts would have no obvious benefit in the treatment of dry eye. An obviousness rejection cannot be based on picking and choosing from among numerous choices and then changing the amount of the selected component. Leahy provides absolutely no motivation for any such selecting or changing.

In response, the Examiner states that applicants have argued "Leahy does not discloses (sic) very small amounts of preservatives..." Applicants have made no such statement. Correction by the Examiner is requested. To the contrary, small amounts of preservative, when present, distinguish Leahy from the present invention.

The Examiner also points out that the claims are directed to compositions and that intended uses are not accorded patentable weight. This may be true but has nothing to do with the patentability of the claims. The Examiner then states that: "A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art". Clarification of this statement is requested since it is not seen how the recitation of an intended use can result in a structural difference. The Examiner further states that: "If the prior art structure is capable of performing the

intended use, then it meets the claim." This cannot possibly be correct, as a matter of law. The statement means that a second structure, no matter how different it is from a first structure, cannot be patented if it has the same purpose as the first. A citation for this statement is requested. This statement also appears to contradict the Examiner's earlier statement quoted above regarding structural differences.

The Examiner states that no demonstration of unexpected results has been made. None are needed here. An argument made on the basis of unexpected results is used to rebut an Examiner's rejection based on *prima facie* obviousness. In the present case, it is deemed that the Examiner has not made a rejection based on *prima facie* obviousness for the reasons provided herein.

On page 3 of the Action, paragraph 1 ends with: "And thus,". The meaning of this is unclear; clarification is requested.

In response to applicant's argument that an obviousness rejection cannot be based on picking and choosing from among numerous choices and then changing the amount of the selected component, especially since Leahy provides absolutely no motivation for any such selecting or changing, the Examiner answers that picking and choosing is not required since compositions containing biguanide are taught by Leahy. The Examiner has completely ignored the issue of the amount of biguanide involved. Where, as here, a reference teaches zero biguanide or 15 ppm biguanide, it is not obvious that one of ordinary skill in the art would increase the amount of this compound to that presently claimed.

The Examiner then states (page 3, last paragraph) that applicants have provided no factual evidence of the claimed amount of biguanide *vs* the amount in Leahy. This statement is clearly incorrect. The claimed amount of biguanide is provided in claim 1; the amounts in Leahy is provided at col. 8, line 60 (*i.e.*, zero biguanide) and in the examples cited by the Examiner. No more factual evidence is deemed necessary. Further in this paragraph, the Examiner argues that differences "in amounts of the disintegration agent...will not support the patentability of the subject matter encompassed by the prior art". The meaning of this statement is unclear for two reasons. First, there are no

disintegration agents in the claims or the prior art. Second, the present claims are not "encompassed" by the prior art. "Encompassed" suggests that the patent application is one of selection, which might lead to a rejection for anticipation under 35 U.S.C. § 102. However, the claims are not within the scope of Leahy and no such rejection is being made. Clarification of this statement is requested.

Leahy neither suggests compositions which do not contain the compounds now excluded from claim 4 nor does it suggest the additional compositions recited in claim 5.

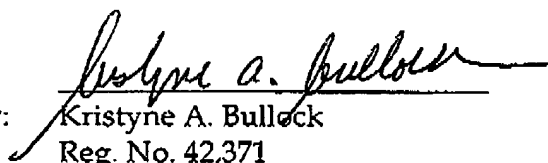
Claims 1 and 3 are rejected under 35 U.S.C. § 103 as obvious over Ellis (United States Patent No. 6,277,365) or Tetsuhisa (JP 2000-109892). Claim 2 is free of this art. Claim 1 has now been re-drafted as claim 4, which incorporates the subject matter of canceled claim 2. Therefore, the rejection is deemed moot.

It is requested that the amendment be entered since it reduces the number of claims, places the claims in condition for allowance, and/or place the claims in better condition for appeal. It is requested that the Examiner reconsider the rejections in view the amendment and remarks.

Respectfully submitted,

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Enclosure